JUN - 9 2006

K060402

510 (k) Summary

Submitted on behalf of:

Devon Safety Products
DBA Devon Medical Supplies
1100 First Avenue, Suite 100
King Of Prussia, PA 19406
Telephone: 1-800-431-2273
Fax: 610-768-4509

Submitted by: **Paladin Medical, Inc.**
P.O. Box 560
Stillwater, MN 55082
Telephone: 715-549-6035
Fax: 715-549-5380

CONTACT PERSON: **Elaine Duncan**

DATE PREPARED: March 10, 2006
TRADE NAME: **SafeTip Safety Syringe**
COMMON NAME: Safety Syringe
REGULATION: Piston Syringe: 21 CFR 880.5860: Class II
General Hospital Product code: MEG and FMI

SUBSTANTIALLY EQUIVALENT TO:
The Devon Medical Supplies SafeTip Syringe is substantially equivalent to the Medisys Tech. CoverTip Safety Syringe for technological features, the Becton Dickinson Integra Syringe in performance and the Devon Standard Syringe for materials.

DESCRIPTION of the DEVICE:
The SafeTip Safety Syringe is a piston syringe that features a passive sharp safety feature which covers the needle after injection. The syringe automatically deploys a plastic cover (sheath) over the needle as the injection is completed and prior to the needle's removal from the tissue. The sheath protrudes beyond the end of the needle, shielding the user and patient from the sharp needle after removal.

INDICATIONS FOR USE:
The SafeTip Syringe is indicated for use in the administration of an intramuscular (IM) injection. The SafeTip Safety Syringe aids in the prevention of accidental needle sticks by passively and automatically deploying a sheath that covers the sharp needle upon completion of the injection

SUMMARY of TESTING:
The Devon SafeTip Safety Syringe has been shown to meet internationally recognized standards for syringe performance and labeling characteristics. Simulated clinical use testing has demonstrated the performance of the SafeTip syringe and reliability of the safety feature in accordance with the FDA Guidance: *Medical Devices with Sharps Injury Prevention Features*: August 9, 2005.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 26 2006

Mr. G. Baskaran
Group Managing Director
Brightway Holdings Sdn. Bhd.
Lot 1559, Jalan Istimewa,
Batu Belah
Klang, Selangor, Darul Ehsan
MALAYSIA 42100

Re: K060402
Trade/Device Name: BRIGHTWAY™ Brand Nitrile Examination Gloves
(Powder Free, Chlorinated, Black Colour)
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LZA
Dated: May 31, 2006
Received: June 7, 2006

Dear Mr. Baskaran:

This letter corrects our substantially equivalent letter of June 13, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

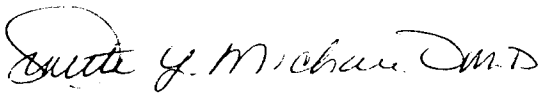
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

3.0 **Indications for Use**

510(k) number : K 060402

Device Name : BRIGHTWAY™ Brand Nitrile Examination Gloves (Powder Free, Chlorinated, Black Color)

Indications for use:

BRIGHTWAY™ Brand Nitrile Examination Glove (Powder Free, Chlorinated, Black Color) is a disposable patient examination glove which is worn on the hand of healthcare and similar personnel to prevent contamination between patient and examiner.

Prescription Use _____ AND / OR Over – The - Counter Use __X___
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Linda A Mingkey M.D.
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
(Division Sign-Off) Number K060402